



## **MRAIA**

### **Business Associate Agreement**

This Agreement is made effective the \_\_\_\_\_ of \_\_\_\_\_, 201\_\_\_\_, by and between \_\_\_\_\_, hereinafter referred to as “Covered Entity”, and Medical Research Analytics and Informatics Alliance, LLC, hereinafter referred to as “Business Associate”, (individually, a “Party” and collectively, the “Parties”).

WITNESSETH:

WHEREAS, Sections 261 through 264 of the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, known as “the Administrative Simplification provisions,” direct the Department of Health and Human Services to develop standards to protect the security, confidentiality and integrity of health information; and

WHEREAS, pursuant to the Administrative Simplification provisions, the Secretary of Health and Human Services issued regulations modifying 45 CFR Parts 160 and 164 (the “HIPAA Security and Privacy Rule”); and

WHEREAS, the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5), pursuant to Title XIII of Division A and Title IV of Division B, called the “Health Information Technology for Economic and Clinical Health” (“HITECH”) Act, provides modifications to the HIPAA Security and Privacy Rule (hereinafter, all references to the “HIPAA Security and Privacy Rule” are deemed to include all amendments to such rule contained in the HITECH Act and any accompanying regulations, and any other subsequently adopted amendments or regulations); and

WHEREAS, the Parties wish to enter into or have entered into an arrangement whereby Business Associate will provide certain services to Covered Entity, and, pursuant to such arrangement, Business Associate may be considered a “business associate” of Covered Entity as defined in the HIPAA Security and Privacy Rule (the agreement evidencing such arrangement is entitled DATA CONFIDENTIALITY AND RELEASE AGREEMENT WITH MEDICAL RESEARCH ANALYTICS AND INFORMATICS ALLIANCE, dated 05/23/2012, and is hereby referred to as the “Arrangement Agreement”); and

WHEREAS, Business Associate may have access to Protected Health Information (as defined below) in fulfilling its responsibilities under such arrangement;

THEREFORE, in consideration of the Parties’ continuing obligations under the Arrangement Agreement, compliance with the HIPAA Security and Privacy Rule, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, and intending to be legally bound, the Parties agree to the provisions of this Agreement in order to address the requirements of the HIPAA Security and Privacy Rule and to protect the interests of both Parties.

#### **I. DEFINITIONS**

Except as otherwise defined herein, any and all capitalized terms in this Section shall have the definitions set forth in the HIPAA Security and Privacy Rule. In the event of an inconsistency between

the provisions of this Agreement and mandatory provisions of the HIPAA Security and Privacy Rule, as amended, the HIPAA Security and Privacy Rule shall control. Where provisions of this Agreement are different than those mandated in the HIPAA Security and Privacy Rule, but are nonetheless permitted by the HIPAA Security and Privacy Rule, the provisions of this Agreement shall control.

The term “Protected Health Information” means individually identifiable health information including, without limitation, all information, data, documentation, and materials, including without limitation, demographic, medical and financial information, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual. “Protected Health Information” includes without limitation “Electronic Protected Health Information” as defined below.

The term “Electronic Protected Health Information” means Protected Health Information which is transmitted by Electronic Media (as defined in the HIPAA Security and Privacy Rule) or maintained in Electronic Media.

Business Associate acknowledges and agrees that all Protected Health Information that is created or received by Covered Entity and disclosed or made available in any form, including paper record, oral communication, audio recording, and electronic display by Covered Entity or its operating units to Business Associate or is created or received by Business Associate on Covered Entity’s behalf shall be subject to this Agreement.

## II. CONFIDENTIALITY AND SECURITY REQUIREMENTS

### (a) Business Associate agrees:

(i) To use or disclose any Protected Health Information solely: (1) for meeting its obligations as set forth in any agreements between the Parties evidencing their business relationship, or (2) as required by applicable law, rule or regulation, or by accrediting or credentialing organization to whom Covered Entity is required to disclose such information or as otherwise permitted under this Agreement, the Arrangement Agreement (if consistent with this Agreement and the HIPAA Security and Privacy Rule), or the HIPAA Security and Privacy Rule, and (3) as would be permitted by the HIPAA Security and Privacy Rule if such use or disclosure were made by Covered Entity. All such uses and disclosures shall be subject to the limits set forth in 45 CFR § 164.514 regarding limited data sets and 45 CFR § 164.502(b) regarding the minimum necessary requirements;

(ii) At termination of this Agreement, the Arrangement Agreement (or any similar documentation of the business relationship of the Parties), or upon request of Covered Entity, whichever occurs first, if feasible, Business Associate will return or destroy all Protected Health Information received from or created or received by Business Associate on behalf of Covered Entity that Business Associate still maintains in any form and retain no copies of such information, or if such return or destruction is not feasible, Business Associate will extend the protections of this Agreement to the information and limit further uses and disclosures to those purposes that make the return or destruction of the information not feasible;

(iii) To ensure that its agents, including a subcontractor, to whom it provides Protected Health Information received from or created by Business Associate on behalf of Covered Entity, agrees to the same restrictions and conditions that apply to Business Associate with respect to such information, and agrees to implement reasonable and appropriate safeguards to protect any of such information which is Electronic Protected Health Information. In addition, Business Associate agrees to take reasonable steps to ensure that its employees' actions or omissions do not cause Business Associate to breach the terms of this Agreement;

(iv) Business Associate shall, following the discovery of a breach of unsecured PHI, as defined in the HITECH Act or accompanying regulations, notify the covered entity of such breach pursuant to the terms of 45 CFR § 164.410 and cooperate in the covered entity's breach analysis procedures, including risk assessment, if requested. A breach shall be treated as discovered by Business Associate as of the first day on which such breach is known to Business Associate or, by exercising reasonable diligence, would have been known to Business Associate. Business Associate will provide such notification to Covered Entity without unreasonable delay and in no event later than One (1) calendar day after discovery of the breach. Such notification will contain the elements required in 45 CFR § 164.410; and

(v) Business Associate will, pursuant to the HITECH Act and its implementing regulations, comply with all additional applicable requirements of the Privacy Rule, including those contained in 45 CFR §§ 164.502(e) and 164.504(e)(1)(ii), at such time as the requirements are applicable to Business Associate. Business Associate will not directly or indirectly receive remuneration in exchange for any PHI, subject to the exceptions contained in the HITECH Act, without a valid authorization from the applicable individual. Business Associate will not engage in any communication which might be deemed to be "marketing" under the HITECH Act. In addition, Business Associate will, pursuant to the HITECH Act and its implementing regulations, comply with all applicable requirements of the Security Rule, contained in 45 CFR §§ 164.308, 164.310, 164.312 and 164.316, at such time as the requirements are applicable to Business Associate.

(b) Notwithstanding the prohibitions set forth in this Agreement, Business Associate may use and disclose Protected Health Information as follows:

(i) If necessary, for the proper management and administration of Business Associate or to carry out the legal responsibilities of Business Associate, provided that as to any such disclosure, the following requirement is met:

(A) The disclosure is required by law

(c) Business Associate will implement appropriate safeguards to prevent use or disclosure of Protected Health Information other than as permitted in this Agreement. Business Associate will implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of any Electronic Protected Health Information that it creates, receives, maintains, or transmits on behalf of Covered Entity as required by the HIPAA Security and Privacy Rule.

(d) The Secretary of Health and Human Services shall have the right to audit Business Associate's records and practices related to use and disclosure of Protected Health Information to ensure Covered Entity's compliance with the terms of the HIPAA Security and Privacy Rule.

(e) Business Associate shall report to Covered Entity any use or disclosure of Protected Health Information which is not in compliance with the terms of this Agreement of which it becomes aware. Business Associate shall report to Covered Entity any Security Incident of which it becomes aware. For purposes of this Agreement, "Security Incident" means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system. In addition, Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement.

### III. AVAILABILITY OF PHI

Business Associate agrees to comply with any requests for restrictions on certain disclosures of Protected Health Information pursuant to Section 164.522 of the HIPAA Security and Privacy Rule to which Covered Entity has agreed and of which Business Associate is notified by Covered Entity. Business Associate agrees to make available Protected Health Information to the extent and in the manner required by Section 164.524 of the HIPAA Security and Privacy Rule. If Business Associate maintains Protected Health Information electronically, it agrees to make such Protected Health Information electronically available to the applicable individual. Business Associate agrees to make Protected Health Information available for amendment and incorporate any amendments to Protected Health Information in accordance with the requirements of Section 164.526 of the HIPAA Security and Privacy Rule. In addition, Business Associate agrees to make Protected Health Information available for purposes of accounting of disclosures, as required by Section 164.528 of the HIPAA Security and Privacy Rule and Section 13405(c)(3) of the HITECH Act. Business Associate and Covered Entity shall cooperate in providing any accounting required on a timely basis.

### IV. TERMINATION

Notwithstanding anything in this Agreement to the contrary, Covered Entity shall have the right to terminate this Agreement and the Arrangement Agreement immediately if Covered Entity determines that Business Associate has violated any material term of this Agreement. If Covered Entity reasonably believes that Business Associate will violate a material term of this Agreement and, where practicable, Covered Entity gives written notice to Business Associate of such belief within a reasonable time after forming such belief, and Business Associate fails to provide adequate written assurances to Covered Entity that it will not breach the cited term of this Agreement within a reasonable period of time given the specific circumstances, but in any event, before the threatened breach is to occur, then Covered Entity shall have the right to terminate this Agreement and the Arrangement Agreement immediately.

### V. MISCELLANEOUS

Except as expressly stated herein or the HIPAA Security and Privacy Rule, the Parties to this Agreement do not intend to create any rights in any third parties. The obligations of Business Associate

under this Section shall survive the expiration, termination, or cancellation of this Agreement, the Arrangement Agreement and/or the business relationship of the Parties, and shall continue to bind Business Associate, its agents, employees, contractors, successors, and assigns as set forth herein.

This Agreement may be amended or modified only in a writing signed by the Parties. No Party may assign its respective rights and obligations under this Agreement without the prior written consent of the other Party. None of the provisions of this Agreement are intended to create, nor will they be deemed to create any relationship between the Parties other than that of independent parties contracting with each other solely for the purposes of effecting the provisions of this Agreement and any other agreements between the Parties evidencing their business relationship. This Agreement will be governed by the laws of the State of North Carolina. No change, waiver or discharge of any liability or obligation hereunder on any one or more occasions shall be deemed a waiver of performance of any continuing or other obligation, or shall prohibit enforcement of any obligation, on any other occasion.

The Parties agree that, in the event that any documentation of the arrangement pursuant to which Business Associate provides services to Covered Entity contains provisions relating to the use or disclosure of Protected Health Information which are more restrictive than the provisions of this Agreement, the provisions of the more restrictive documentation will control. The provisions of this Agreement are intended to establish the minimum requirements regarding Business Associate's use and disclosure of Protected Health Information.

In the event that any provision of this Agreement is held by a court of competent jurisdiction to be invalid or unenforceable, the remainder of the provisions of this Agreement will remain in full force and effect. In addition, in the event a Party believes in good faith that any provision of this Agreement fails to comply with the then-current requirements of the HIPAA Security and Privacy Rule, including any then-current requirements of the HITECH Act or its regulations, such Party shall notify the other Party in writing. For a period of up to thirty days, the Parties shall address in good faith such concern and amend the terms of this Agreement, if necessary to bring it into compliance. If, after such thirty-day period, the Agreement fails to comply with the HIPAA Security and Privacy Rule, including the HITECH Act, then either Party has the right to terminate upon written notice to the other Party.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the day and year written above.

COVERED ENTITY:

BUSINESS ASSOCIATE:

By: \_\_\_\_\_

By: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_